



EFSPi Annual Report 2006

Highlights

- Successful meetings (co-) organized, including the DIA meeting on Statistical Methodology in Clinical R&D in Heidelberg, one in Basel “Statistical Methods and Concepts for Programmers” and a workshop on “Adaptive Randomisation” in Brussels in December.
- Thorough review of Reflection paper on Flexible Designs, with a better and more interactive procedure.
- Decision to re-design our website to make it more attractive and also easier to maintain and use for EFSPi’s objectives and membership.
- Substantial improvement of our financial position.

Council membership

In 2006, there were 10 countries within EFSPi, each represented by their national association of pharmaceutical statisticians, with a combined membership of around 2000. Members of the EFSPi Council at the end of 2006 are given in the Appendix.

Paul Koopman was thanked for his long standing and exceptional and valuable contribution to EFSPi over a very long period of time, including a Presidency. Paul Koopman was succeeded by Gonnie van Osta on behalf of the Dutch member organisation. Paul Koopman, as well as past Presidents Karsten Schmidt and Bernhard Huitfeldt who stepped down earlier, were presented with a small gift as token of EFSPi’s appreciation.

At the Council meeting October 2006 in Heidelberg Nigel Howitt was elected as Vice-President, succeeding Merete Jørgensen. Merete decided to stay on the Council. Her role over the years has been substantial in EFSPi’s development over the years.

Council meetings

Two Council meetings were held in 2006. The first took place in Amsterdam, The Netherlands. Ten members were present, representing 7 member groups.

The second meeting was held in Heidelberg, Germany in conjunction with the DIA workshop on Statistical Methodology in Clinical R&D. Ten members were present, representing 8 member groups.

Regulatory affairs

During 2006 we refined the procedure for review and consolidation of comments. The changes were to give greater focus on the major comments and to produce a more consolidated Industry view than previously.

In 2006 the Reflection Paper on Flexible Designs was reviewed according to the new procedure. The new way of consolidating comments was appreciated and seems to have improved the quality of our comments.

Scientific Affairs

EFSPI council members has been the driving force behind the Statistical workshop on Statistical Methods in Clinical R&D in Heidelberg 2006, which include a very interesting discussion session with industry statisticians, academia and regulatory statisticians. A range of contemporary topics were covered. A joint meeting with PSI on “Statistical Methods and Concepts for Programmers” was successfully held in Basel in February. In addition, a workshop on “Adaptive Randomisation” was held in Brussels in December, jointly organised with EORTC. This was fully booked with over 60 delegates and was a success.

The meetings organised have turned out financially interesting, where the profits made can be used to ensure a financially sound position for EFPSI and increase our service to our member organisations and their individual members.

Preparations for the Joint conference with PSI Brussels (planned for May 2008) were also started and EFPSI / PSI collaboration was officially arranged.

Web-facilities

The major development for the website was the decision to have a redesign done by a professional agency. The objectives were to make the website more attractive, but importantly, also to make it easier to maintain and use for EFSPI’s objectives and membership. In 2006, at the October Council meeting, the decision to do so was taken and vendor selection was done. EFSPI’s website is an important asset, which offers an easy access to information and important links for our member organisations. All members are encouraged to use the site for advertising and any comments on content and functionality of the website we ask you kindly to feed back to the webmaster.

Qualification Affairs

The publication based on answers to a questionnaire to EFSPI’s member organisations on Qualifications of Statisticians in the Pharmaceutical Industry was still in progress. We hope to finalize this in 2007.

Executive Office

The Executive Office facility continues to be provided by Resources for Associations at Macclesfield (UK). During 2006 Laura Kennedy has provided support for EFSPI, and she was joined by Helen King to ensure continuity.

Finances

Reports of Income and Expenditure for 2005 were approved by the honorary auditors. The budget and member group fees for 2007 were agreed, the change of fee calculation (excluding the provisional “ability to pay” factor as well as the last remaining continuity correction related to size of the member organization) has now been fully implemented. *Statements on 2006 results not included because they await accountant’s advice.*

APPENDIX: Members of the EFSPI Council at the end of 2004

Belgium

Cecile Dubois, UCB S.A. Cecile Dubois
Catherine Legrand, Merck Sharp & Dohme (Europe), Inc.

Denmark

Merete Jorgensen, Novo Nordisk A/S
Arne Haahr Andreasen, Andreasen Statistical Consulting

Finland

Britt-Marie Lindström, Oy 4Pharma Ltd
Toni Sarapohja, Orion Pharma

France

Florence Casset-Semanaz, Glaxo Smith Kline Serono
Francois Aubin, Laboratoires Fournier

Germany

Marlis Herbold, Aventis GmbH (in 2006 replaced by Joachim Roehmel)
Frank Langer, Lilly Deutschland GmbH

Italy

Francesca Patarnello, GlaxoSmithKline

Netherlands

Paul Koopman, Solvay Pharmaceuticals (in 2006 replaced by Gonnie van Osta, Organon)
Kit Roes, Organon

Sweden

Carl Fredrik Burman, AstraZeneca
Mikael Astrom, Clinical Data Care

Switzerland

Gerd Rosenkranz, Novartis Pharma AG
Fred Sorenson, Analytica International, European Office

UK

Nigel Howitt, PRA International
Lesley France, AstraZeneca